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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,625	02/01/2001	Jana Sawynok	DALHO1290-1	7582

7590

09/10/2003

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 09/10/2003

27

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/700,625

Applicant(s)

SAWYNOK ET AL.

Examiner

Lakshmi S Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26,37-44,49-53 and 72-83 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26,37-44,49-53 and 72-83 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt of request for extension of time and request under 37 CFR 1.114 dated 8-25-03 is acknowledged.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8-25-03 has been entered.

Claims 26, 37-44, 49-53 and 72-83 are pending in the instant application.

The following is a new rejection:

Claim Rejections - 35 USC § 112

1. Claims 37-41, 73 and 79-83 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Instant claims are amended to exclude the second and third generation antidepressants that are not 5-HT₂ receptor antagonists, which is not supported by the specification. Instant specification does not describe or exemplify compositions containing second and third generation antidepressants with the claimed negative limitation and accordingly is anew matter.

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If applicants wish to claim all the second and third generation antidepressants other than 5-HT₂ receptor antagonists, it is suggested that applicants list the desired compounds in a markush format.

Claim Rejections - 35 USC § 102

2. Claims 26, 42-44, 49-53 and 72 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,290,986 to Murdock et al (hereafter Murdock).

Murdock discloses transdermal compositions containing bupropion in the form of a Pluronic gel mixed with soya lecithin (C7, example 5, L 45-62 & C 13, example 31). Murdock teaches the carriers, and polymer such as Pluronic. Further, Murdock discloses compositions in the form of gel containing robexetine (C 14, example 45). Claim 51 recites for local injection, which is an intended use and carries no patentable distinction.

Therefore, Murdock anticipates instant claims.

The following rejection of record (paper #22) has been maintained in view of the above “new matter rejection”:

3. Claims 37-43 and 73, 74, 76, 79 and 81 are rejected under 35 U.S.C. 102(b) as being anticipated by Amer (US 5,266,571, hereafter ‘571).

4. Claims 75, 77, 78, 80, 82 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amer (US 5,266,571, hereafter ‘571) in view of Knepp et al (hereafter Knepp).

Response to Arguments

Applicant's arguments filed 8-25-03 have been fully considered but they are not persuasive.

Applicants argue that '571 discloses only serotonin (5-HT₂) antagonists, as effective for treatment of hemorrhoids, whereas the instant claims recite second and third generation antidepressants. Applicants presented the same arguments with respect to rejection of claims as being unpatentable over Amer in view of Knepp. While applicants agree that certain compounds, such as nefazodone, fall in both classes, they state that instant claim amendment specifically excludes such compounds solely to advance the prosecution and that '571 cannot anticipate instant claims. However, the argument is not persuasive because as explained in the new matter rejection (see above). The specific exclusion is not supported by the instant specification and as also suggested by the examiner (above) if applicants wish exclude certain compounds, it is suggested that applicants list all the other compounds that do not fall under the category of serotonin antagonists. Therefore, the rejection is deemed proper.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 703-308-2438. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Lakshmi S Channavajjala
Examiner
Art Unit 1615

September 3, 2003